Joint UKBTS / HPA Professional Advisory Committee (*)

Position Statement

The estimated risk that a donation entering the blood supply is a potentially infectious window period donation: risks specific for HBV, HCV and HIV in the UK, 2010 – 2011.

November 2012

Prepared by: The Standing Advisory Committee on Transfusion Transmitted Infections (SACTTI)

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Summary

- Although current blood donation testing strategies minimise the risk of transfusion transmitted infections in the UK, on very rare occasions potentially infectious donations are not detected and may enter the blood supply. This is perhaps mostly because a blood donation is made during the potentially infectious 'window period' (WP) early in the course of infection when the test in use will not detect the marker of infection.

- Here, we calculate window period risk as the risk multiplied by 1 million, which is the number of potentially infectious donations in 1 million donations entering the blood supply, and the number of donations entering the blood supply before 1 of those donations can be expected to be a potentially infectious donation.

- The estimated number of potentially infectious window period donations per million donations tested that entered the UK blood supply during 2010-2011 was 0.76, 0.036 and 0.15 for HBV, HCV and HIV respectively.

- At current donation levels of approximately 2.5 million donations each year, testing is estimated to *NOT* identify approximately two potentially infectious HBV window period donations every year, one potentially infectious HCV window period donation every 10 years and one potentially infectious HIV window period donation every 2.7 years.

- Donations from new donors that enter the blood supply were estimated to be more likely to be infectious compared with donations from repeat donors.

- Of the three viruses, HBV was the virus most likely to be missed due to a window period donation during 2010-2011.

- The estimated risk for HCV has increased compared with estimates published in 2010 because of an increased number of seroconversions detected in established donors.

- Despite anti-HTLV testing of blood donations in the UK, the risk is not estimated. This is because of (i) the uncertainty about the presence and/or duration of an infectious window period for HTLV and (ii) the relevance of the calculation, given that widespread leucodepletion of all components is likely to significantly reduce onwards transmission to patients.

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Table 1: The estimated risk (and 95% confidence interval) that a donation entering the UK blood supply is a potentially infectious HBV, HCV or HIV window period donation: 2010-2011.

Risk due to window period		**HBV[1]**	**HCV[2]**	**HIV[3]**
Number of potentially infectious window period donations in 1 million donations entering the blood supply (95% CI). This is equal to risk x 1,000,000	All donations	0.76 (0.22-1.61)	0.036 (0.015 - 0.070)	0.15 (0.09 - 0.32)
	Donations from new donors	2.19 (0.55-5.84)	0.146 (0.043- 0.394)	0.21 (0.02 – 1.79)
	Donations from repeat donors	0.62 (0.18 - 1.26)	0.025 (0.010-0.044)	0.15 (0.09-0.22)
Number of donations (millions) entering the blood supply before 1 of those donations can be expected to be a potentially infectious donation. This is equal to 1/(risk x 1,000,000)	All donations	1.32	28	6.47
	Donations from new donors	0.46	6.9	4.81
	Donations from repeat donors	1.61	40	6.69

1. HBV testing assumed all donations were tested for markers of HBsAg and HBV DNA using NAT with a window period of 38.3 days. However, Scotland did not commence HBV NAT testing until March 2010.
2. Anti-HCV testing and HCV RNA testing with a window period 4 days.
3. Combined HIV antigen/antibody testing and HIV NAT with a window period 9 days.
4. The risk due to WP amongst all donations was calculated as the weighted average of the risk amongst new and repeat donors, weighted according to the number of donations made from new and repeat donors.

   Note: All NAT testing was on pooled samples of 24 donations.

These estimates were produced using data collected by the NHSBT/HPA epidemiology unit. Data are checked regularly to ensure data quality, however, data may be revised if new or additional information is received. Please acknowledge NHSBT/HPA Epidemiology Unit when quoting these data.

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